

Remarks

Claims 1-6, 8-64 and 73-79 are pending in the application. Claims 65-72 stand withdrawn from consideration. Claim 76 has been added, which combines the features of method claim 61 and device claim 33. Claims 77-79 are based upon claims 62-64. Claims 1, 2, 8, 10, 11 13-26, 28-34, 39-42, 44-53, 55-64 and 73-75 have been rejected. Claims 3-6, 9, 12, 27, 35-38, 43 and 45 have been objected to as being dependent upon a rejected base claim abut would be otherwise allowable if written in independent form including all of the limitations of the base claims and any intervening claims.. Reconsideration is respectfully requested in view of the following remarks.

Response to Rejections Under 35 U.S.C. §112

Claims 61-64 have been rejected as allegedly indefinite, because it is alleged that a method claim cannot depend from a device claim. Examiner has indicated that claim 61 should be amended to recite the limitations of the base device claims.

Claim 61 has been amended to independent form, and includes the features of the device of claim 1. Claim 76 has been added, which combines the features of claim 61 and device claim 33. Accordingly, applicants respectfully submit that the rejection under 35 U.S.C. §112 is overcome.

Response to Rejections Under 35 U.S.C. §102 and 103

Claims 1, 2, 8, 10, 11, 13-15, 18-21, 23, 32-34, 39-42, 44-48, 50, 58, 61 and 64 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by D'Augustine *et al.* ("D'Augustine").

The rejection is based upon the incorrect statement that "D'Augustine discloses a urethral suppository (col. 9, line 63) for insertion into a female urethra". There is no disclosure of a urethral suppository at D'Augustine col. 9, line 63. There is no disclosure of a urethral suppository anywhere in col. 9 of D'Augustine. For that matter, there is no disclosure of a urethral suppository anywhere in the four corners of D'Augustine.

Col. 9, l. 52+ discloses a *vaginal* drug delivery device for delivery of a drug to the *vaginal* epithelium and mucosa, for the treatment of *vaginal* infection or diseases . The device may take the form of a tampon, tampon-like device, vaginal ring, pessary, cup, vaginal ring, cervical cup or vaginal sponge (l. 56-58). As an alternative to a tampon or tampon-like device for vaginal drug delivery, D'Augustine describes a "sponge, suppository or other absorbent material impregnated with a liquid drug...shaped into a tampon-fitting device" (l. 62-66). The D'Augustine vaginal suppository embodiment is not a *urethral* suppository. There is no mention anywhere in D'Augustine of insertion of a device of any kind into the urethra, let alone a suppository. Clearly, the suppository teaching seized upon by Examiner in col. 9 is not a urethral suppository, but merely a vaginal suppository that is formed to fit into the vagina. This is clear from a reading of col. 9, lines 51-67, and the indication that the suppository is shaped so as to be "tampon-fitting". A device which is "tampon-fitting" is adapted and sized for insertion into the vagina, not the urethra.

It is respectfully submitted that Examiner has erred in attributing to D'Augustine a disclosure of a urethral suppository for insertion into a female urethra. There is no such teaching at col. 9, line 63, or anywhere else in the disclosure of D'Augustine.

The Examiner has improperly taken the tangential disclosure of a vaginal suppository from col. 9 and has attributed to the Fig. 6 device the function as a suppository. This is incorrect. D'Augustine's tangential teaching of a "sponge, *suppository* or other absorbent material impregnated with a liquid drug...shaped into a tampon-fitting device" does not mean that every structure disclosed in the four corners of D'Augustine automatically becomes a *suppository*. The Fig. 6 device which forms the basis of the anticipation rejection is not a suppository. It is a tampon ("Fig. 6 is a cross-sectional representation of...a *tampon* drug delivery system" (col. 15, l. 5-7, emphasis added). Furthermore, the device is not for insertion into the urethra, but into the vagina. The device is shown inserted into a vagina in Fig. 6, not into a urethra. The device is clearly not a urethral suppository.

The claimed invention is directed to a urethral suppository, not a vaginal tampon as described by D'Augustine. The preamble language "urethral suppository" gives "life and

meaning" to the claim, and therefore serves as a limitation. *See Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). Where, as here, the claim preamble is part of the definition of the invention, it constitutes a claim limitation. *See Diversitech Corp. v. Century Steps, Inc.*, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988).

As urged by applicants in the Amendment Under 37 C.F.R. 1.116 filed May 28, 2004, a "suppository" is "[a] small solid body shaped for ready introduction into one of the orifices of the body other than the oral cavity (e.g., rectum, urethra, vagina), made of a substance, usually medicated, which is solid at ordinary temperature but melts at body temperature". *PDR Medical Dictionary*, 1st ed., Medical Economics, Montvale, New Jersey, 1995, p. 1706 (of record). The body of the D'Augustine vaginal device is not meltable but is principally composed of materials which do not melt. The materials disclosed for the porous foam portion (43) are polyurethane, polyester, polyether and collagen. These materials are not meltable at body temperature. The *absorbent tampon* (45) part of the D'Augustine Fig. 6 device is also not meltable. A "tampon" is "[a] cylinder or ball of cotton-wool, gauze or other loose substance; used as a plug or pack in a canal or cavity to restrain hemorrhage, absorb secretions, or maintain a displaced organ in position". *PDR Medical Dictionary* p. 1761 (of record). Designed to form an obstruction against discharge of blood or other secretions, a tampon can not be meltable at body temperature, since it would fail for its intended purpose. A tampon must remain intact to perform its blockage function.

The claimed invention is directed to a urethral suppository comprising a meltable portion that contains a medication. Consistent with the dictionary definition of "suppository", the meltable portion is inserted as a solid and melts as it reaches body temperature. This means the urethral suppository of the invention will be inserted with the shape and structure of the meltable portion surrounding the reinforcing member. The meltable portion will then melt as it reaches body temperature until the meltable portion is completely gone. The device upon removal will have the shape and structure of the reinforcing member only. In contrast, the shape and structure of the D'Augustine Fig. 6 device is not effected by the process of insertion and removal. Hence,

it is clear that the D'Augustine Fig. 6 device is not a urethral suppository, and does not anticipate the present claims.

Examiner alleges that the elements of claims 1, 33, 61 and 64 can be found in the D'Augustine Fig. 6 device as follows:

“a non-meltable base member (47); a non-meltable reinforcement (44) having a length, said length having a first end (proximal portion of 44) and a second end (distal portion of 44), said first end attached to said base member and projecting from said base member (see Figure 6); and a meltable portion (medicine, col. 15, line 24) formed around a portion of said length of said reinforcement, said meltable portion having a diameter which tapers from said second end toward said first end (see fig. 6).”

Examiner alleges that the D'Augustine plastic loop (47) is the non-meltable base member feature of the claimed invention. D'Augustine's loop (47) is not a non-meltable base member. Moreover, the rejection incorrectly ignores an element of the claims. The claims recite not just a non-meltable base member, but a base member which is *not for insertion* into the urethra. The base member serves as a stop for limiting the insertion of the suppository into the urethra.

As explained in the Amendment Under 37 C.F.R. 1.116 filed May 28, 2004, D'Augustine tube (44) to which the loop (47) is connected is embedded entirely in the porous foam portion (43) and tampon portion (45) of the D'Augustine device. The primary function of the tube (44), is a conduit for blood, while the loop (47) serves merely as an attachment point for a removal string (See col. 15, line 20). The loop (47) is not a base member. A “base” is defined in *Webster's Collegiate Dictionary*, G. & C. Merriam Company, Springfield, MA, 1977, p. 92 (of record) as “the bottom of something considered as its support”.

Located in the interior of the D'Augustine device, loop (47) does not function as a base for the Fig. 6 device, and cannot function to limit the insertion of the device into any body channel, let alone a urethra. Loop (47) is buried in the center of the tampon (45) portion of the device and can not contact any body surfaces. Loop (47) merely serves as an attachment structure for string (48), which is used to withdraw the tampon device from the vagina. Masked by the surrounding absorbent material of tampon (45), cannot interact with any body structure to limit the insertion of the device into a body channel. Loop (47) is not adapted to prevent

insertion into the urethra. It is in fact easily inserted in the vagina with the other portions of the D'Augustine device. Considering the size of the loop with respect to the size of the surrounding tampon, it is expected that loop would have a diameter of about 1/10th the diameter of a typical vaginal tampon. Even assuming *arguendo* that the loop could be utilized in an intraurethral device (which is not suggested by D'Augustine), it would not be prevented from entering the urethra.

In conclusion, D'Augustine plastic loop (47) can not be construed as applicants' non-melttable base member which is not for insertion into the urethra.

Furthermore, non-porous tube (44) of the D'Augustine device is not a "reinforcement" according to the claimed invention. The function of the reinforcement in the claimed invention is to make the suppository stiffer, lending structural support during insertion, and to hold the melttable portion in place as it dissolves in the urethra. There is no reference in D'Augustine to the function of tube (44) as a reinforcement. D'Augustine describes (44) as "non-porous plastic tube which conducts blood flow to the absorbent tampon" (col. 15, lines 11-12). No reference is made in D'Augustine of the tube possessing any strength or lending support to the device during insertion. The function of a tube runs counter to the concept of reinforcement as tubes will buckle when exposed to lateral forces.

In conclusion, independent claims 1 and 33 are not anticipated by D'Augustine.

Claims 61 and 76 are directed to methods which utilize the devices of claims 1 and 33. Since claims 1 and 33 are not anticipated, claims 61 and 76 are also free of the rejection. Notwithstanding, applicants offer the following remarks regarding the asserted ground of rejection.

As to claim 61, Examiner alleges that a method for delivering therapeutic agents to the female urinary tract using "the suppository" is disclosed in by D'Augustine at col. 5, line 20 and col. 7, line 60. Nowhere in the four corners of his patent does D'Augustine teach inserting a device into the urethra. The D'Augustine devices are for intravaginal delivery of drugs or transvaginal delivery of drugs. Both routes of administration require insertion of a device into the vagina. Once the device of D'Augustine is in place in the vagina, drug released into the

vagina can travel through the vaginal mucosa (*transvaginal* delivery) to reach other tissues, e.g., the urethra. While drug released from the device inserted into the vagina may cause a therapeutic effect in the uterus (col. 5, line 20 and col. 7, line 60) this is not a teaching of insertion of a device *into the urethra*. The claimed invention includes the step of inserting a suppository into the female urethra, not the vagina.

The passages in D'Augustine seized upon by Examiner do not disclose drug delivery to the urethra, but rather intravaginal drug delivery with systemic absorption of drug which makes its way to the urinary tract through the circulatory system.

It is respectfully submitted that claims 1, 33, 61 and 76, constituting the independent claims of the application, are not anticipated by D'Augustine.

The inventions of claims 1, 33, 61 and 76 would not have been obvious to one of ordinary skill in the art at the time the invention was made in view of the referenced disclosure of D'Augustine. The D'Augustine Fig. 6 device is a drug-delivering vaginal tampon, not a urethral suppository. The claimed urethral suppository is so markedly different in structure and function from the reference's vaginal tampon that there would be no incentive for one skilled in the art to modify the latter to arrive at the former. Intravaginal and intraurethral devices are not interchangeable. The modifications of the D'Augustine required to arrive at the claimed urethral suppository would result in the destruction of the D'Augustine device for its intended purpose as a vaginal tampon.

The examiner states in her Section 103 rejection that D'Augustine teaches that the "suppository" is for treatment of various medical conditions in various body parts, citing col. 5, lines 12-20 as support. The D'Augustine device is solely for intravaginal drug delivery and could not be used in other organs. The effect of the device described by D'Augustine on other organs, including the urethra, is a secondary affect caused by the systemic absorption of drug through the vagina. Passing through the circulation, the drug affects all organs in the body, not just the urethra. None of the embodiments of the D'Augustine device could function in the same manner or achieve the results of the claimed device for urethral drug delivery. D'Augustine does not disclose a urethral suppository, nor is the current invention obvious from the teachings

of D'Augustine. There is no similarity between the elements of D'Augustine and those of the claimed invention.

The various secondary references do not remedy the deficiencies of D'Augustine. It is respectfully submitted that claims 1, 33, 61 and 76, constituting the independent claims of the application, are not rendered obvious by the asserted prior art.

The remaining claims in the application depend either directly or indirectly from claims 1, 33 or 61. In view of the allowability of these claims, the remaining claims under examination are also allowable.

The claims of the application are believed to be in condition for allowance. An early action toward that end is earnestly solicited.

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